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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/768,093	02/02/2004	Marcia K. Wolf	034047.033.4	6121

7590 11/13/2006

Office of the Staff Judge Advocate
U.S. Army Medical Research and Materiel Command
ATTN: MCMR-JA (Ms. Elizabeth Arwine)
504 Scott Street
Fort Detrick, MD 21702-5012

EXAMINER

GRASER, JENNIFER E

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 11/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/768,093

Applicant(s)

WOLF ET AL.

Examiner

Jennifer E. Graser

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1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 August 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10,11,16-22,25,26 and 31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10,11,16-19 and 31 is/are rejected.
- 7) ☒ Claim(s) 20-22 and 26 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Acknowledgment and entry of the Amendment submitted on 8/23/06 is made.

Claims 10, 11, 16-22, 25, 26 and 31 are currently pending.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 10, 11, 25 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolf et al (different inventive entity) (Submitted. Jan. 1994. UniProt Accession # P53509).

Wolf et al disclose a protein which is 100% identical to Applicants' SEQ ID NO: 9. The compositions of claims 11 and 25 only require the protein. However, the protein disclosed by Wolf et al contains the N-terminal signal sequence so it is 18 amino acids longer than that of Applicant's SEQ ID NO:9 which does not contain the signal sequence. It was well known in the prior art at the time the invention was made that the N-terminal, hydrophobic sequences which are mediate the attachment of newly translated polypeptide chains to intracellular membranes in secretory proteins, such as the one which is claimed, is cleaved off during expression. See

'<http://crisp.cit.nih.gov/Thesaurus/00006706.htm>'. The Wolf et al reference specifically recites that amino acids 1-18 are the 'signal peptide'. Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made that to express the protein and achieve the protein minus the signal sequence, which would be identical to SEQ ID NO:9. The recombinant expression methods known in the art were well known at the time the invention was made.

Response to Applicant's Arguments:

Applicants argue that the claims have been limited to 'consisting of' and, therefore, the protein disclosed by Wolf et al does not anticipate the claims. This argument has been addressed in the rejection set forth above.

Claim Rejections - 35 USC § 102/103

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 10, 11, 16, 17, 18, 19, 25 and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Wolf et al (1989, Infect.Immun. 57(1): 164-173) or, in the alternative, under 35 U.S.C. 103(a) as obvious over by Wolf et al (1989, Infect.Immun. 57(1): 164-173).

Wolf et al. disclose compositions that comprise CS6 protein from *E.coli* E8775, the same strain from which the protein of SEQ ID NO: 9 was isolated. One of the

disclosed compositions that comprised CS6 proteins was an agarose gel containing the CS6 16 kDa band (Figure 3, a type of acceptable carrier). An additional composition that comprised the W8775 CS6 protein was a saline extract of E8775 (see page 167, col. 1, paragraph 1). The protein was used to generate antisera. Additionally, it was shown that the whole cell bacterium raised antibodies against the CS6 protein. Wolf et al do not disclose the amino acid sequence of E8775 16kDa protein CS6, but the amino acid sequence of a protein is an inherent structural characteristic. Inherently the reference anticipates the now claimed invention. *Atlas Powder Co. V IRECA*, 51 USPQ2d 1943, (FED Cir. 1999) states Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art...However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior arts functioning, does not render the old composition patentably new to the discoverer. The Court further held that this same reasoning holds true when it is not a property but an ingredient that is inherently contained in the prior art.

The disclosed protein of the prior art reference appears to be identical to Applicants' protein given the identity of the source. Since the Patent Office does not have the facilities for examining and comparing Applicant's BPIP with the BPIP of the prior art, the burden of proof is upon applicants to show an unobvious distinction between the material structural and functional characteristics of the claimed protein and the protein of the prior art. See In re Best, 195 USPQ 430, 433 (CCPA 19&&).

Response to Applicants' Arguments:

Applicants argue that Wolf et al does not teach the polypeptide because a polypeptide similar to SEQ ID NO:9, such as #P533509, would be expected to result in an eluted band in a gel in a position substantially similar to SEQ ID NO:9. They argue that the protein of the diluted band could be easily mistaken for one or the other without a suitable control and thus, it is unclear that the protein of the eluted band is SEQ ID NO:9 rather than #p53509. They argue that Wolf et al does not disclose the sequence of the eluted band used to generate the antisera. These arguments have been fully and carefully considered but are not deemed persuasive.

Wolf et al do not disclose the amino acid sequence of E8775 16kDa protein CS6, but the amino acid sequence of a protein is an inherent structural characteristic.

Inherently the reference anticipates the now claimed invention. Atlas Powder Co. V IRECA, 51 USPQ2d 1943, (FED Cir. 1999) states Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art...However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior arts functioning, does not render the old composition patentably new to the discoverer. The Court further held that this same reasoning holds true when it is not a property but an ingredient that is inherently contained in the prior art. Wolf et al. disclose compositions that comprise CS6 protein from *E.coli* E8775, the same strain from which the protein of SEQ ID NO: 9 was isolated. One of the disclosed compositions that comprised CS6 proteins was an agarose gel containing the CS6 16 kDa band (Figure 3, a type of acceptable carrier). An additional composition that comprised the W8775 CS6 protein was a saline extract of E8775 (see page 167, col. 1,

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paragraph 1). The protein was used to generate antisera. Additionally, it was shown that the whole cell bacterium raised antibodies against the CS6 protein.

Applicants have not shown that the protein taught by Wolf et al does not elute in a gel in a similar position to that of SEQ ID NO:9.

Claim Rejections - 35 USC § 112 2nd paragraph

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 19 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 19 recites that the polypeptide is administered in the form of a 'host cell that expresses the polypeptide and that the host cell is 'killed'. It is unclear how a killed host cell and express the polypeptide. It does not appear that a killed host cell would display the protein and, therefore, an antigenic response against the polypeptide would not be generated. Clarification and/or correction is requested.

Claims 20-22 and 26 are objected to as being dependent upon a rejected base claim.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Correspondence regarding this application should be directed to Group Art Unit 1645. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Remsen. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Group 1645 Fax number is 571-273-8300 which is able to receive transmissions 24 hours/day, 7 days/week.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer E. Graser whose telephone number is (571) 272-0858. The examiner can normally be reached on Monday-Thursday from 7:30 AM-6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can be reached on (571) 272-0974.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-0500.


Jennifer Graser
Primary Examiner
Art Unit 1645

11/11/08

GenCore version 5.1.7
Copyright (c) 1993 - 2006 Bioacceleration Ltd.

OM protein - protein search, using ew model

Run on: April 10, 2006, 10:13:49 ; Search time 230 Seconds
(without alignment)
417.182 Million cell updates/sec

Title: US-10-768-093-9

Perfect score: 699

Sequence: 1 RTEIATKNFPVSTTISKSPF.....EKKISPGIYNDQVMVGYVN 136

Scoring table: BLOSUM62
Gapop 10.0 , Gapext 0.5

Searched: 2166443 seqs, 705528306 residues

Total number of hits satisfying chosen parameters: 2166443

Minimum DB seq length: 0
Maximum DB seq length: 2000000000

Post-processing: Minimum Match 04
Maximum Match 1004
Listing first 45 summaries

Database : Uniprot 05.80: *
1: uniprot_sprot: *
2: uniprot_trembl: *

* Pred. No. is the number of results predicted by chance to have a score greater than or equal to the score of the result being printed, and is derived by analysis of the total score distribution.

SUMMARIES

Result No.	Score	Query Match	Length	DB ID	Description
1	699	100.0	154	1	P6A2_ECOLI
2	655	93.7	154	1	P6A1_ECOLI
3	120.5	17.2	167	1	P6B1_ECOLI
4	113.5	16.2	167	1	P6B2_ECOLI
5	92	13.2	440	2	Q5AUS8_DICDI
6	87	12.4	918	2	Q72P30_LEPIC
7	87	12.4	918	2	Q8F7D7_LEPIN
8	83	11.9	749	2	Q81IA3_BACCR
9	83	11.9	12268	2	Q8MO08_CABEL
10	83	11.9	13100	2	Q09165_CABEL
11	82	11.7	248	2	Q6HQE5_BACAN
12	82	11.7	248	2	Q630P3_BACCK
13	82	11.7	248	2	Q6HASE_BACHK
14	82	11.7	264	2	Q81J04_BACAN
15	82	11.7	268	2	Q4MGG1_BACCE
16	82	11.7	279	2	Q84214_9BACT
17	82	11.7	287	2	Q72X92_BACCI
18	82	11.7	524	2	Q6CDU2_YARLI
19	81.5	11.7	449	2	Q87125_VIBPA
20	81.5	11.7	454	2	Q89706_CLOTE
21	81.5	11.7	610	2	Q5WV11_LEGPL
22	81.5	11.7	610	2	Q5X443_LEGPA
23	81.5	11.7	610	2	Q5ZUD2_LEGPH
24	81	11.6	318	2	Q4K1L8_STRPN
25	81	11.6	318	2	Q4K105_STRPN
26	81	11.6	595	2	Q8YUL1_ANASP
27	81	11.6	1047	2	Q9RB35_9SPHI
28	81	11.6	1818	2	Q88207_MOUSE
29	80.5	11.5	360	1	ARCC_HAEPU
30	80.5	11.5	1303	1	Q4WH6_4SPFU
31	80	11.4	251	2	Q814R6_BACCR

32	80	11.4	279	2	Q84219_9BACT
33	80	11.4	316	2	Q523K0_MAGCR
34	80	11.4	440	2	Q8A503_BACTN
35	80	11.4	1936	2	Q4QDF6_LEIMA
36	79.5	11.4	385	2	Q7RKR4_PLAYO
37	79.5	11.4	459	2	Q8D3R5_VIBVU
38	79.5	11.4	826	2	Q8DX37_STRAS
39	79	11.3	1372	2	Q5PB95_ANAMM
40	79	11.3	1840	2	Q9J103_BAT
41	78.5	11.2	279	2	Q5K2B9_9BACT
42	78.5	11.2	279	2	Q5K2F1_9BACT
43	78.5	11.2	279	2	Q5K2F7_9BACT
44	78.5	11.2	279	2	Q5K2F9_9BACT
45	78.5	11.2	279	2	Q5K2H9_9BACT

Wolferd. Submitted 1/94

ALIGNMENTS

RESULT 3
P6A2_ECOLI STANDARD; PRT; 154 AA
AC PS1509;
DT 01-OCT-1996 (Rel. 34, Created)
DT 01-OCT-1996 (Rel. 34, Last sequence update)
DT 10-MAY-2005 (Rel. 47, Last annotation update)
DE CS6 fimbrial subunit A precursor (CS6 pilin).
GN Name=cs6A;
OS Escherichia coli.
OC Bacteria; Proteobacteria; Gammaproteobacteria; Enterobacteriales;
OC Enterobacteriaceae; Escherichia.
OX NCBI_TaxID=562;
RN [1]
RP NUCLEOTIDE SEQUENCE.
RC STRAIN=B8775;
RA Wolf M.K., de Haan L.A.M., Cassels P.C., Willehaw G.A., Gestel E.C.M.,
RA Gaasstra W., Warren R., Boedeker E.C.;
RL Submitted (JAN-1994) to the EMBL/GenBank/DBJ databases.
CC -!- FUNCTION: Fimbriae (also called pili), polar filaments radiating
CC from the surface of the bacterium to a length of 0.5-1.5
CC micrometers and numbering 100-300 per cell, enable bacteria to
CC colonize the epithelium of specific host organs.
CC
CC This Swiss-Prot entry is copyright. It is produced through a collaboration
CC between the Swiss Institute of Bioinformatics and the EMBL outstation -
CC the European Bioinformatics Institute. There are no restrictions on its
CC use as long as its content is in no way modified and this statement is not
CC removed.
CC
CC EMBL; U04846; AA051361.1; -; Unassigned_DNA.
CC Fimbria; Signal
CC SIGNAL 1 138
CC CDSIN 19 134
CC CS6 fimbrial subunit A.
CC SEQUENCE 154 AA; 16940 MW; 4218223D9FA5FCB8 CRC64;
Query Match 100.0%; Score 699; DB 1; Length 154;
Best Local Similarity 100.0%; Pred. No. 1.28-56; Indels 0; Gaps 0;
Matches 136; Conservative 0; Mismatches 0;
Oy 1 RTEIATKNFPVSTTISKSPFAPRIQPSFGENVGKALLFSVNLTPENVSVQVTVPV 60
Db 19 RTEIATKNFPVSTTISKSPFAPRIQPSFGENVGKALLFSVNLTPENVSVQVTVPV 78
Oy 61 YDEYDGLRLVNTADASQSIYQIVDEKQKMLKDHGAVTPNQOITPKALNTSGKKI 120
Db 79 YDEYDGLRLVNTADASQSIYQIVDEKQKMLKDHGAVTPNQOITPKALNTSGKKI 138
Oy 121 SPGIYNDQVMVGYVN (136)
Db 139 SPGIYNDQVMVGYVN 154

RESULT 2

1-18 are signed